

Serial No.: 10/537,187  
 Case No.: 21208Y  
 Page No.: 24

RECEIVED  
 CENTRAL FAX CENTER

REMARKS

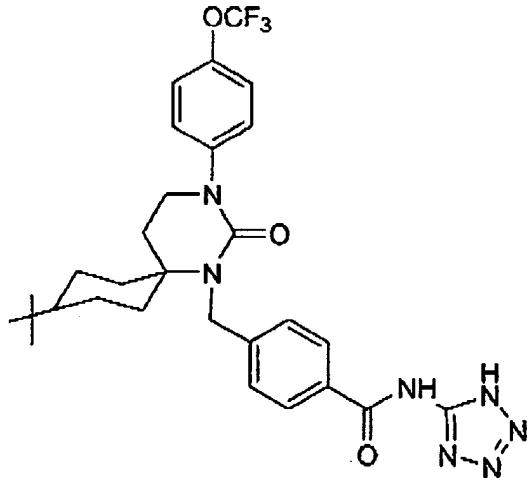
DEC 19 2007

Reconsideration and allowance of the captioned patent application are respectfully requested. This Amendment is in response to the restriction and election of species requirements and the rejection of the claims under 35 USC 112 paragraph one for lack of enablement.

Applicants provisionally elected group XVIII, compounds of formula I, in which X represents CH<sub>2</sub>, one of a and b is 1, and ring Y represents a cycloalkyl ring. This election is confirmed without traverse.

The claims have been amended in response to this restriction, with the understanding the Applicants are entitled to file divisional applications to address non-elected groups, and may traverse the restriction as it has been applied to the non-elected subject matter at that time. Applicants do not agree that restriction is appropriate between all of the designated groups as described by the Examiner.

The Examiner also required an election of species. Applicants designated the compound of the formula:



Applicants confirm this election. This compound is elected for purposes of facilitating the Examiner's search of the art and with the understanding that the election requirement will be withdrawn by the Examiner upon determining that an allowable generic claim exists. Claims that encompass the elected specie are claims 1-3 and 6-21.

Serial No.: 10/537,187  
Case No.: 21208Y  
Page No.: 25

Claims 1, 6, 7, 16, 17, 18 and 19 have been amended. Claims 4 and 5 have been cancelled. Claim 21 was withdrawn from consideration by the Examiner, as drawn to a non-elected invention.

The rejection of claims 4 and 5 is rendered moot by cancelling these claims. Applicants respectfully traverse the rejection of claims 1-3, 6-18 and 20 for non-enablement.

The Examiner has indicated that the application is enabling for compounds in which R<sup>1</sup> represents alkyl, cycloalkyl, optionally substituted phenyl or benzyl and Y represents t-butylcyclohexyl. This indication is appreciatively acknowledged. However, Applicants respectfully disagree that the application is non-enabling with respect to the remaining subject matter. Applicants have provided six generic schemes and 105 examples of compounds and the synthesis thereof, that fall within the genus of formula I. These generic schemes and examples are applicable to the synthesis of compounds within group VXIII either directly or by close analogy. For example, with respect to R<sup>1</sup>, the full scope of R<sup>1</sup> is enabled in view of general scheme 4, in which compound 7 is not limited to R<sup>1</sup> equal to alkyl, cycloalkyl, optionally substituted phenyl and benzyl. Substituted C<sub>1-15</sub> alkyl and cycloalkyl groups, and aryl and heteroaryl groups at this position would be relatively simple for the skilled chemist to make, taking into account the teachings contained in the application and the high level of technical skill that a PhD chemist would have in this field. It is well within the level of skill in the art to select suitable R<sup>1</sup> groups and to make and use such compounds, taking into account the teachings of the specification.

The enabled values of ring Y are no different. Generic Scheme 1 provides more than sufficient guidance for all possible values within the definition of ring Y. The ring Y precursor ketone is used as a simple starting material, enabling one of ordinary skill to incorporate any substituted or unsubstituted Y group into the desired molecule without undue experimentation. The generic schemes taken in conjunction with Examples 99-102 provide more than sufficient guidance for the skilled chemist to make compound in which the Y ring is varied substantially.

The Examiner cited three cases in support of his position that the application is non-enabling. Applicants disagree that these cases support the Examiner's allegation of non-enablement. In U.S. v. Teletronics (Teletronics), the claim at issue contained "means plus function" language, significantly broader than the language of the present claims. Teletronics was held to have been enabled by the

Serial No.: 10/537,187  
Case No.: 21208Y  
Page No.: 26

disclosure of one embodiment, namely a stainless steel electrode. Applicants in the present case have provided over a hundred examples, far beyond the disclosure that was provided in *Teletronics*. In *Ex parte Forman (Foreman)*, the Appellants claimed an entire class of oral vaccines that consisted of hybrid bacteria that had been genetically engineered to produce an immunizing effect against typhoid and one other non-typhoid enteric disease. *Foreman* sets forth the factors to be considered in determining whether the extent of experimentation required is "undue". The Board in *Forman* noted the art was undeveloped with respect to the strains of microorganisms that would have been useful, and

there was not even a single example which could be followed to obtain a single, specific vaccine within the claims. There was a complete lack of examples in *Foreman* is in contrast to the present application. As noted above, Applicants urge that the chemistry described in the present application is more than enabling, taking into account the numerous generic synthesis schemes and over a hundred examples. Merely setting forth a standard as in *Foreman* for what constitutes "undue experimentation" does not support the Examiner's allegation that the present application is non-enabled. Applicants have more than met the *Foreman* standard. Lastly, *In re Wands* is another decision that focused on biotechnology. *Wands* relates to an immunoassay and methods for detecting hepatitis B surface antigen using high affinity monoclonal IgM antibodies. The applicants in *Wands* provided a single deposit in conjunction with a written description, and the question on appeal was whether the specification in *Wands* enabled the ordinarily skilled artisan to make the monoclonal antibodies needed to practice the invention. The Federal Circuit held that the written specification fully enabled the claimed invention irrespective of the deposit that was made. Significant factors in *Wands* were the use of readily available starting materials, the employment of conventional procedures to produce hybridomas, and routine screening procedures, searching for biologically active high affinity monoclonal antibodies. One deposit taken in conjunction with the written description rendered the invention enabled. Again, Applicants in the instant case have provided numerous generic schemes, and more than sufficient exemplifications to meet the enablement requirement.

Given the level of experimentation that was deemed to be routine and not "undue" within *Wands*, there should be no question that the claimed compounds are fully enabled, since virtually no experimentation would be required to make and use the compounds of formula I according to the teachings of the specification. Applicants therefore urge that the enablement requirement has been met. Withdrawal of this rejection is therefore respectfully requested.

Serial No.: 10/537,187  
Case No.: 21208Y  
Page No.: 27

Based on the foregoing, it is urged that the captioned patent application is in condition for allowance. Such action is respectfully requested. If the Examiner has any questions in connection with the application, he is requested to telephone the undersigned.

Respectfully submitted,

By



Richard C. Billups, Reg. No. 31,916  
Attorney for Applicants

MERCK & CO., Inc.  
P.O. Box 2000  
Rahway, New Jersey 07065-0907  
Tel: (732)594-4683

Date: December 19, 2007